IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF VIRGINIA Alexandria Division

TRIANTAFYLLOS TAFAS,	
Plaintiff,)
v.) Case No. 1:07cv846 (JCC/TRJ)
JON W. DUDAS, et al.,)
Defendants.)
CONSC	DLIDATED WITH
SMITHKLINE BEECHAM CORPORATION, et al.,	
Plaintiff,)
v.) Case No. 1:07cv1008 (JCC/TRJ)
JON W. DUDAS, et al.,)
Defendants.)

DECLARATION OF JOHN W. MANZETTI IN SUPPORT OF AMICUS CURIAE THE PENNSYLVANIA GREENHOUSES' BRIEF IN SUPPORT OF PLAINTIFFS' ANTICIPATED MOTIONS FOR SUMMARY JUDGMENT

I, John W. Manzetti, do hereby state the following:

1. I am President and Chief Executive Officer of the Pittsburgh Life Sciences Greenhouse ("PLSG").

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- 2. PLSG is funded by the state and local foundations. PLSG, one of three Pennsylvania Greenhouses, was initially funded by monies received from the Commonwealth of Pennsylvania's share of The Tobacco Settlement Act of 2001. PLSG has received additional monies from the Commonwealth of Pennsylvania, as well as from local foundations and returns on its investments.
- 3. PLSG provides capital investments and customized company formation and business growth services to life sciences companies in southwestern Pennsylvania. PLSG promotes the relationship between research, technology, and commercialization with capital investment and business growth programs that have been specifically tailored to the needs of southwestern Pennsylvania's life sciences industry. PLSG primarily focuses on guiding researchers, entrepreneurs and emerging companies through the difficult challenges faced in the early stages of company development. By helping them build sustainable business models and secure capital investments, PLSG helps deliver biomedical innovations to the marketplace more quickly and efficiently.
- 4. PLSG typically supports life sciences companies developing product and service innovations in medical devices, therapeutics, diagnostics/screening, biotechnology services, and healthcare information technology. As the only organization exclusively dedicated to the growth of the life sciences industry in southwestern Pennsylvania, PLSG connects entrepreneurs with new streams of capital. While follow-on investment is encouraged, PLSG can invest up to \$1 million in portfolio companies.
- 5. Since 2002, PLSG has committed \$9.5 million directly in 47 life sciences companies, which have attracted \$300 million in additional capital. Representative investments

include Cardiorobotics, Inc., which is a medical device company focusing on highly articulated robotic probes; Cellatope Corp., which is developing diagnostics for auto-immune diseases such as lupus; and Immunetrics, which provides tools for drug discovery and clinical diagnostics of inflammatory diseases. Other activities and information on companies associated with PLSG are described in Appendix A attached hereto.

- 7. Patent protection is vital to the companies in which PLSG invests. Each stage of funding by PLSG in an early-stage life science companies depends, in large part, on the company's ability to obtain patents on the technologies and products that it has developed.
- 8. In my experience, the ability to obtain clear and comprehensive patent protection is a key element in attracting necessary additional capital investment, as well as corporate partners necessary to commence the costly research and development of life science inventions. Sustaining an adequate, ever-increasing level of financing and partnering during continued research and development, clinical investigations, regulatory approval and commercialization of a life science product depends upon a funded company's ability to obtain comprehensive patent protection. The ability of an early-stage life science company to obtain capital is therefore directly tied to its intellectual property assets and particularly to its patent portfolio.
- 9. I am generally familiar with the final rules published by the United States Patent and Trademark Office ("PTO") on August 21, 2007 as Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46,716 (Aug. 21, 2007) (hereinafter "Final Rules") (to be codified at 37 C.F.R. pt. 1).

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- 10. PLSG opposes implementation of the Final Rules because, among other things, the Final Rules will shift the burden of examination onto patent applicants by requiring the preparation of an "Examination Support Document," which will lead to an increase in legal fees, as well as unfairly restricted opportunities for obtaining patent protection.
- 11. In my experience, life science product development is extremely expensive. Early-stage life science companies will be adversely affected if they are forced to allocate additional funds toward patent prosecution as a result of the proposed changes to the PTO's rules.
- 12. If a life science company were to lose its basic patent coverage or be forced to give up the protections afforded by current continuation application practice, it is possible that PLSG and other investors may decline the next stage or round of investment because of the loss of patent exclusivity and the resulting economic disincentive to develop and commercialize new products.
- 13. In my experience, early-stage life science companies rely heavily on the certainty of the patent system to attempt to secure market exclusivity on any inventions so as to enable those companies and their investors to recover their investments. PLSG and its funded companies rely heavily on patent protection, as well as the current, established PTO rules of practice, to obtain adequate coverage for inventions and to attract the necessary financial investment to research, develop and commercialize life science products.
- 14. I declare under penalty of perjury that to the best of my knowledge the foregoing is true and correct.

John W. Manzetti
President and Chief Executive Officer
Pittsburgh Life Sciences Greenhouse

APPENDIX A